

Information Disclosure Statement.

Applicants respectfully request that objections to the Information Disclosure Statement be held in abeyance until claims are allowed.

Rejections Under 35 USC §112, First Paragraph.

The Examiner has rejected Claim 1 under the first paragraph of 35 USC §112 as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time of filing. In view of the amendment to Claim 1, this rejection should no longer apply.

Rejection Under 35 USC §112, First Paragraph.

The Examiner has rejected Claim 1 under the first paragraph of 35 USC §112 for an alleged lack of enablement. In view of the amendment to Claim 1, this rejection should no longer apply.

Rejections Under 35 USC §102.

The Examiner has rejected Claim 1 under 35 USC §102(b) as allegedly being anticipated by either Grey et al. (hereinafter "Grey") or Cheever et al. (hereinafter "Cheever"). Applicant hereby respectfully argues against this rejection for the reasons set forth below.

First, the Cheever cited art is not prior art against the instant application. The instant application is a divisional of United States Patent Application Serial No. 08/860,232 filed June

13, 1997. That application is the U.S. national phase filing of PCT Application Serial No. 95/16415, which PCT application claims priority of United States Patent Application 08/355,558 filed December 14, 1994. Thus the priority date of the instant application, December 14, 1994 is earlier than either the issue date or the filing date of the cited Cheever art. The Cheever cited art therefore is not prior art against the instant application. Applicants therefore respectfully request withdrawal of the 102 rejection based on Cheever.

Applicants respectfully argue against the alleged anticipatory effect of the Grey cited art on the basis that the art does not disclose each and every element of the claimed invention. The Grey cited art does not disclose the effect of any antigen, let alone the specifically recited peptide of Claim 1, to specifically activate cytotoxic T lymphocytes *in vivo*, wherein those lymphocytes specifically target malignant cells that express a human Her-2/Neu protein. The Examiner has credited Grey as teaching peptides which elicit an immune response. The Examiner has not, however, provided any evidence whatsoever that, at the time the present invention was made, there was a known correlation between immunogenicity and the ability to activate cytotoxic T cells. It is unlikely that such a direct correlation exists and, indeed, specific teachings of the Grey disclosure argue against such a correlation. By way of example, the peptide WILRGTSFV (see Table 25, page 83) is disclosed as having immunogenic activity. In contrast, that same peptide (see Table 24, page 77) is shown to have no measurable cytotoxic activity. In light of the above, Applicants respectfully request withdrawal of the 102 rejection based on Grey.

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TSRI 433.1 D4



SUMMARY

In view of the amendment to the claim and for the reasons set forth above, Applicant respectfully submits that the claim is now in a condition of allowance. An early notification to that effect is hereby earnestly solicited.

Respectfully submitted,

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Date

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APPENDIX A

1. (Amended) A polypeptide capable of specifically activating cytotoxic T lymphocytes *in vivo*, wherein said cytotoxic T lymphocytes (CTLs) specifically target malignant cells that express a Her-2/Neu protein, wherein the polypeptide has the amino acid residue sequence of SEQ ID NO:10.